Prospective Comparative Study of Gefitinib Therapy for Postoperative Recurrent Non-small Cell Lung Cancer with Epidermal Growth Factor Receptor Mutations

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Abstract：Purpose：This study was designed to investigate the efficacy and feasibility of gefitinib for the treatment of recurrent non-small cell lung cancer (NSCLC) patients after surgery with epidermal growth factor receptor (EGFR) mutations in comparison to conventional chemotherapy for those without EGFR mutations. Patients and Methods：The EGFR gene status of the recurrent NSCLC patients after surgery obtained from formalin-fixed and paraffin-embedded surgical specimens was examined by the DNA sequencing of EGFR exons 18 to 21. Patients with EGFR mutations received gefitinib (250 mg/day), and those without EGFR mutations received conventional chemotherapy. The response rate(RR), disease control rate(DCR), progression free survival (PFS), and toxicity profile were all assessed prospectively. Results：Between October 2005 and May 2007, 17 patients were examined for the EGFR status, and 7 patients(41%) harbored EGFR mutations. EGFR mutations were significantly more frequently found in females (P=0.021) and never smokers (P=0.021). Seven patients with EGFR mutations received gefitinib therapy and six patients without EGFR mutations received conventional chemotherapy. The response rate at 3 months in the gefitinib treated patients was 42.9% (95% CI, 6.2% to 79.6%), and the disease control rate was 71.4%(95% CI, 38% to 100%). The median PFS of these patients was 10.9 months (1.9 to 19.8 months). No life-threatening toxicity was observed. While these parameters in the conventional chemotherapy group were 0%, 16.7%(95% CI, 0% to 46.5%), and 5.4 months(1.1 to 14.2 months), respectively. Conclusion：Treatment with gefitinib for the recurrent NSCLC patients with EGFR mutations was thus found to achieve a high efficacy with acceptable toxicity.

Key words：Gefitinib, Non-small cell lung cancer, Prospective study, EGFR mutations, Postoperative recurrence